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K002084
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Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

Appendix D: Regulatory Submission Summary (510k Summary)

Submission Summary (per 21 CFR 808.92)

Sponsor:	Boston Scientific Corporation (BSC) One Scientific Place Natick, MA 01760-1537
Contact Person:	Lorraine M. Hanley, RAC Division Manager of Regulatory Affairs, Microvasive Urology, BSC or Robert J. Michalik, RAC Senior Regulatory Affairs Specialist
Submission Date:	July 5, 2000
Common/Usual Names: **Trade/Proprietary Name:**	Endoscopic Intracorporeal Pneumatic Lithotriptor Probe To be Determined
Device Classification and Name:	Boston Scientific Corporation believes that, while the proposed device is classified as Class III, a Class II classification is more appropriate for this device. A request for reclassification of this device in accordance with 515(I) is currently under review. • CFR 876-4480; Lithotriptor, Electro-hydraulic Product Code: 78FFK
Substantial Equivalence:	The proposed device is *substantially equivalent* to other currently marketed devices used for fragmenting urinary calculi, including renal, ureteral and bladder stones, through rigid, semi-rigid and flexible endoscopes.
Product Testing:	The proposed device is *substantially equivalent* to other currently marketed lithotripsy devices in terms of performance characteristics tested and biocompatibility.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 9 2000

Mr. Robert J. Michalik, RAC
Senior Regulatory Affairs Specialist
Microvasive Urology
Boston Scientific Corporation
One Boston Scientific Place
Natick, MA 01760-1537

Re: K002084
Microvasive® Lithotriptor® Flexprobe II™
Dated: July 6, 2000
Received: July 10, 2000
Regulatory Class: II
21 CFR 876.4480/Procode: 78 FFK

Dear Mr. Michalik:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

SECTION III: - INDICATIONS FOR USE ENCLOSURE.

510(k) Number (if known): K002084

Device Name: Microvasive® Lithotriptor® FlexProbe II ™

Indications For Use:

An endoscopic intracorporeal pneumatic lithotriptor probe for use in ~~fragmenting urinary calculi~~, including renal, ureteral and bladder stones through rigid, semi-rigid and flexible endoscopes.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David G. Lyon
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K002084